

**REMARKS**

Claims 123-127, 141-142, and 149-158 were pending in the present application. By virtue of this response, claims 123-127, 141-142, and 149-158 have been amended. Accordingly, claims 123-127, 141-142, and 149-158 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

**Rejections under 35 U.S.C. §112**

Claims 123-127, 141, 142 and 149-158 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being incomplete for omitting essential elements, such as omission amounting to a gap between the elements.

In response, independent claim 123 has been amended to recite “a stimulator in electrical communication with the at least one electrode whereby the stimulator receives phrenic nerve activity detected internally within the patient’s body in response to respiration sensed by at least one electrode”. Independent claims 126 and 153 have been similarly amended.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

**Rejections under 35 U.S.C. §102**

A. Claims 123-127, 141, 142 and 149-158 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Ignagni et al. (U.S. Pub. 2005/0021102).

In response, independent claim 123 has been amended to recite “a stimulator in electrical communication with the at least one electrode whereby the stimulator receives phrenic nerve activity detected internally within the patient’s body in response to respiration sensed by at least one electrode, wherein the stimulator is programmed to generate an electrical stimulation signal in response to the sensed respiration and deliver the electrical stimulation signal through the at least one electrode to the diaphragm or phrenic nerve tissue”. (Specification, [0038]-[0039] & [0045]-[0048].) Independent claims 126 and 153 have been similarly amended.

disclose a stimulator capable of dispensing stimulation after sensed respiration due to phrenic nerve activity, as submitted by the Office.

Scheiner et al. states that its device “can be used for sensing respiratory activity by a method such as minute ventilation ... and/or for delivering diaphragm therapy by delivering an electric stimulus to phrenic nerve 102 ....” (Scheiner et al., 3: 40-44.) While Scheiner et al. may disclose the delivery of stimulus to the phrenic nerve, it fails to show or describe a stimulator which receives detected phrenic nerve activity but instead discloses respiration sensing through indirect methods.

For example, Scheiner et al. discloses that minute ventilation “can be estimated by frequent measurements of transthoracic impedance between a tip electrode and a pulse generator can electrode when a low energy pulse is delivered from a ring electrode every 50 milliseconds. By measuring the frequency of respiration-related fluctuations in impedance ... and the amplitude of those excursions ..., the estimated minute ventilation can be estimated.” (Scheiner et al. 5: 50-59. Moreover, Scheiner et al. only discloses electrodes which are positioned within or upon the heart. (For example, Scheiner et al., 3: 32-33, 45-49, 62-66 & 4: 14-15, 26-29.) Scheiner et al. also describes another method for estimating respiration by a signal processing circuit 226 which “also can receive signals representative of heart activity such as native depolarization or fibrillation. By filtering the respiratory activity signals from the heart activity signals ....” (Scheiner et al., 5: 63-66.)

Scheiner et al. fails to show or describe any stimulator which receives phrenic nerve activity in response to respiration sensed by an electrode which is in electrical communication with the electrode. Thus, Scheiner et al. cannot anticipate independent claims 123, 126, and 153 and its dependent claims, which are patentable for at least the same reasons.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 USC §102(b).

#### **Rejections under 35 U.S.C. §103**

Claims 123-127, 141, 142 and 149-158 are rejected in the alternative under 35 U.S.C. §103(a) as obvious over Scheiner et al. (US 6,415,183) in view of Meer (US 4,830,008).

On the other hand, Ignagni et al. shows and describes a device which is configured to deliver electrical stimulation on a continuous or periodic basis which is preset. (Ignagni et al., [0030].) Ignagni et al. only describes utilizing physiologic activity where an air flow sensor external to the body can be provided with an external mechanical ventilator for detecting the inspiratory or expiratory air flow. (Ignagni et al., [0035] & Fig. 4.) However, the sensing of air flow is an entirely different mode of sensing from phrenic nerve activity in mechanism and principle. Moreover, the air flow sensor is a sensor which is necessarily positioned external to the patient's body and cannot be said to be internally within the patient's body, as presently claimed.

Thus, Ignagni et al. fails to show or describe a stimulator which is in electrical communication with the at least one electrode through which the stimulator receives phrenic nerve activity indicative of respiration which is detected internally within the patient's body. Furthermore, Ignagni et al. further fails to show or describe such a stimulator which is programmed to generate an electrical stimulation signal in response to the internally sensed phrenic nerve activity. Rather, Ignagni et al. describes the direct sensing of air flow provided by an external mechanical ventilator via a sensor also necessarily located external to the body.

Therefore, Ignagni et al. cannot anticipate independent claims 123, 126, and 153. The dependent claims depend ultimately from claims 123, 126, and 153 and are patentable for at least the same reasons. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejections under 35 USC §102(e).

**B.** Claims 123-127, 141, 142 and 149-158 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Scheiner et al. (US Patent No. 6,415,183).

In response, independent claim 123 has been amended to recite a stimulator which "receives phrenic nerve activity detected internally within the patient's body in response to respiration sensed by at least one electrode." Independent claims 126 and 153 have been similarly amended. Applicant notes that the Office Action states that "Scheiner et al. discloses the device substantially as claimed except for the sensing of the phrenic nerve." (Office Action, p. 6, lines 8-9.) Applicant further contends that Scheiner et al. fails to

In response, Applicant contends that at the least, neither Scheiner et al. nor Meer teach or show “wherein the electrical stimulation signal elicits a diaphragm response such that an inspiration volume is different from an intrinsic inspiration volume of an intrinsic breath”, as presently claimed. Independent claims 126 and 153 similarly recite this feature. Rather, Scheiner et al. teaches a system where electrodes are disposed in and around the heart of a patient for serving the dual purpose of providing phrenic nerve pacing as well as heart pace management. (Scheiner et al., 1: 51-55.)

Moreover, Applicant further contends that when examining each of the inventions of Meer and Scheiner et al., one of ordinary skill in the art would not look to combining the teachings of these inventions given the very purpose and design intent of each as the teachings of Meer teach away from modifying the teachings of Scheiner et al. In combining the teachings of Scheiner et al. and Meer, there must be some reason for the combination other than the hindsight obtained from the invention itself. (It is critical to understand the particular results achieved by the new combination. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 227 USPQ 543 (Fed. Cir. 1985). One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).)

Additionally, there is to expectation of success in the combination of Scheiner et al. with Meer (or any other diaphragmatic pacing reference). Scheiner et al. teaches a device which is used to initiate respiration from a non-breathing patient, which occurs during an episode of sleep apnea. For example, “... the present system is applicable for treating respiratory ailments such as sleep apnea ... [w]hen a physiological state indicating a need for therapy is detected, an electrical stimulus is triggered by a controller, and the electrode delivers an electric stimulus to the phrenic nerve, initiating a respiratory cycle.” (Scheiner et al., 1: 65 – 2: 6.) In other words, Scheiner et al. stimulates the patient in the absence of a breath and not while the patient is breathing and teaches stimulation to treat disordered breathing.

However, in discussing phrenic nerve or diaphragmatic pacing technology, Meer teaches that “... it was found that many of these patients also have some degree of obstructive sleep apnea which worsens when the inspiratory force is augmented by the pacer.” (Meer, 1: 67 – 2: 2.) Meer continues in teaching that “... inspiration can be

stimulated if necessary or inspiration alone can be simulated by causing the diaphragm and other accessory muscles such as the sternomastoid muscles to contract when no inspiratory effort is sensed by the monitor.” (Meer, 2: 49-53.) Thus, Meer teaches that phrenic nerve or diaphragmatic pacing alone is insufficient for treating disordered breathing.

Therefore, the teachings of Meer are directly contrary to the teachings of Scheiner et al. and one of ordinary skill in the art would not look simply to apply the teachings of Meer to that of Scheiner et al. Meer teaches that such a combination, *to wit* as suggested by the Office, would yield an invention where there is no expectation of success and which is directly in opposition to Meer.

Thus, Meer teaches away and simply cannot form a basis to obviate the present invention. Therefore, independent claims 123, 126, and 153 are patentable over Scheiner et al. and Meer, either alone or in combination, and the dependent claims depend therefrom and are patentable for at least the same reasons.

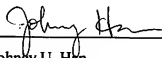
Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 USC §103(a).

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **RMXLNZ00100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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